nanotherapeutics

K110976

SPECIAL 510(K) SUMMARY

Origen DBM® with Bioactive Glass (NanoFUSE® DBM)

MAY - 3 2011

Date: April 6, 2011

Submitted by:
Nanotherapeutics, Inc.
13859 Progress Blvd., Suite 300
Alachua, FL 32615

Representative:
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Senior Vice President of Operations
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Proprietary Name: Origen DBM® with Bioactive Glass (NanoFUSE® DBM)

Common Name: Bone Void Filler, Bone Graft Substitute

Classification Name: Filler, Calcium Sulfate Preformed Pellets, Section 888.3045

Classification Codes: MQV, MBP - Class II

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(k) Number
Origen™ DBM with Bioactive Glass	Nanotherapeutics	K062459

Description:

Origen DBM® with Bioactive Glass (also registered with the FDA as NanoFUSE® DBM) is a malleable, putty-like, bone-void filler for use in general orthopedic applications. The product is comprised of human demineralized bone matrix (DBM) and synthetic calcium phosphor-silicate particulate material particles (45s5 bioactive glass), both coated with gelatin derived from porcine skin. These coated particles are packaged dry in a single use, polypropylene syringe (20 cc or 3 cc), double-wrapped in peel-back pouches, and final packaged in a dust cover paperboard carton. The 20 cc syringe will be filled with either of two different fill quantities of dry powder, identified as 10 cc or 5 cc final product volume. The 3 cc syringe will be filled with dry powder, identified as 2 cc final product volume. Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is intended for single patient use only.

At point of use, the surgeon will reconstitute the product with an appropriate sterile solution of his/her choice (sterile saline, water for injection). The coated particles rehydrate in less than 30 seconds and do not require mixing to form a uniform paste or putty. The material is then gently extruded by the surgeon into the appropriate bone voids. Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is progressively resorbed and replaced by host bone during the osteo-remodeling process.

Indications for Use:	Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. It is indicated to be placed into bony voids or gaps of the skeletal structure (e.g., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. The product provides a bone graft substitute that remodels into the recipient's skeletal system.
Technological Characteristics:	The applicant version of Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is essentially identical to the currently legally marketed medical device Origen DBM® with Bioactive Glass, also manufactured by Nanotherapeutics, Inc. with respect to materials, design, and intended use. The applicant version is comprised of human demineralized bone matrix (DBM) and synthetic calcium phosphor-silicate particulate material particles (45s5 bioactive glass), both coated with gelatin derived from porcine skin. It is provided dry and is reconstituted at the point of use into a paste-like, malleable form that can be molded or manipulated into bony defects. As currently manufactured, the predicate version of Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is reconstituted by the addition of fluid and waiting 30 seconds before expelling the contents from the syringe. At 30 seconds, the product extrudes as a very fluid paste and, with time, the gelatin carrier absorbs the fluid, becomes progressively thicker, and eventually sets in a rubbery mass. The technological characteristics of the applicant device differ from the predicate product only as the manufacturing process has been modified to produce a thicker paste-like form at initial extrusion (i.e. at 30 seconds post reconstitution). The applicant device still becomes progressively thicker until it sets up as a rubbery mass. This modification does not affect the safety or effectiveness of the device. Each lot of DBM used in manufacturing the predicate Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is screened for osteoinductivity in an *in vitro* assay. Each lot of DBM used in manufacturing the applicant version of Origen DBM® with Bioactive Glass (NanoFUSE® DBM) will be screened for osteoinductivity in an *in vitro* assay.
Substantial Equivalence:	The subject of this Special 510(k), the applicant version of Origen DBM® with Bioactive Glass (NanoFUSE® DBM), is produced under a modified manufacturing process to the legally marketed Origen DBM® with Bioactive Glass. Origen DBM® with Bioactive Glass (NanoFUSE® DBM) has the same intended uses and indications and similar technological characteristics as the currently cleared version of Origen DBM® with Bioactive Glass. The minor change in manufacturing process does not alter the fundamental scientific technology of the device and has been shown to have no effect on the safety or effectiveness of the device. Therefore, the applicant version of Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is

substantially equivalent to the currently cleared version of Origen DBM® with Bioactive Glass.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Alachua, Florida 32615

MAY - 3 2011

Re: K110976
Trade/Device Name: Origen™ DBM with Bioactive Glass
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: April 6, 2011
Received: April 7, 2011

Dear Mr. Tomisaka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

nanotherapeutics

INDICATIONS FOR USE

510(k) Number (if known): K110976

Device Name: Origen DBM® with Bioactive Glass (NanoFUSE® DBM)

Indications for Use:

Origen DBM® with Bioactive Glass (NanoFUSE® DBM) is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. It is indicated to be placed into bony voids or gaps of the skeletal structure (e.g., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. The product provides a bone graft substitute that remodels into the recipient's skeletal system.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110976